



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,008	12/21/2004	Joseph K. Belanoff	019904-002210US	7228

20350 7590 03/10/2009
TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

BROOKS, KRISTIE LATRICE

ART UNIT	PAPER NUMBER
----------	--------------

1616

MAIL DATE	DELIVERY MODE
-----------	---------------

03/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/519,008	Applicant(s) BELANOFF, JOSEPH K.	
	Examiner KRISTIE L. BROOKS	Art Unit 1616	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 February 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 1-4 and 8-19.
 Claim(s) withdrawn from consideration: 5-7.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
 13. ☐ Other: _____.

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616

3/06/09

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's arguments are not deemed convincing. Applicant argues that the cortisol levels fall to normal well before IFN- α associated psychotic symptoms arise. Applicant provided several articles that are suppose to suggest that the increase in cortisol is temporary and that there is a delayed onset of psychotic symptoms associated with IFN- α therapy. This argument is not convincing. As discussed prior to, Applicant is not claiming the treatment of a disease, but ameliorating(e.g. . to improve) the symptoms of psychosis associated with IFN- α therapy. Scatzberg et al. teach mifepristone is capable of treating psychosis, the symptoms of psychosis, and psychosis symptoms associated with the side effect of a medication (see column 6 lines 25-32). Thus, one of ordinary skill in the art would have been motivated to try mifepristone for the purpose of reducing the chance of developing psychosis symptoms that may be associated with a medication, i.e., IFN- α therapy.

Applicant argues that the symptoms of psychosis is limited and defined in the specification (see page 4 lines 4-20) and cannot be construed to read on all psychiatric conditions. The instant specification refers to psychosis as a "psychiatric symptom, condition or syndrome in its broadest sense....or as a side effect of a medication,e.g. interferon- α " (see page 4 lines 4-20). Schatzberg et al. also defines psychosis and symptoms of psychosis in the same light (see column 6 lines 25-32). The interpretation of psychosis (and symptoms) is extremely broad as described by Applicant and Schatzberg. Thus, one of ordinary skill can reasonably assume that mifepristone is capable of treating symptoms associated with IFN- α therapy and as described in Ademmer.

1.132 declaration:

Applicant also provided a 1.132 declaration that explains Applicant's position that the increase in cortisol is not associated with IFN- α therapy and thus, one would not have been motivated to use the teachings of Schatzberg et al. This affidavit is not persuasive. Applicant has provided his opinion on the subject matter and references to support his opinion. However, opinions are not given patentable weight when an affidavit is taken into consideration.